REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. With this Amendment and Reply, Applicant petitions for a one-month Extension of Time, with the requisite fee, to extend the due date of the response to the Office Action mailed September 22, 2004 to January 24, 2004 (January 22, 2004 being a Saturday). With this Amendment, claims 1-3 and 6-20 are pending in the application. Each of these claims stand rejected for the reasons outlined below. By this Amendment, claims 1, 6, and 9 are amended to address certain informalities pointed out by the Examiner. Claims 1, 2, 6, 9-12, and 15 are also amended to further clarify Applicant's claimed invention. Claims 4 and 5 are canceled and the subject matter of these claims incorporated into presently amended claim 1. Each of these claim amendments is fully supported by the specification as originally filed and none of these claim amendments introduce new matter.

Claim Objections

Claims 1, 6, and 9 stand objected to. The Examiner presents specific claim amendments that would overcome each of the three bases for objection. In claim 1, line 12, the Examiner recommends replacing [[its]] with the blood transfusion's; in claim 6, line 2, the Examiner recommends deleting [[the blood unit identifying information]]; and in claim 9, line 20, the Examiner recommends replacing [[it]] with the wristband.

Applicant notes that claim 6 is amended as suggested by the Examiner to address the noted informalities. Applicant disagrees, however, with the Examiner's suggestion to amend claim 1 by replacing [[its]] with the blood transfusion's. Rather, Applicant has amended claim 1 by replacing [[its]] with the blood transfusion unit's. Applicant also disagrees with the Examiner's suggestion to amend claim 9 by replacing [[it]] with the wristband. Rather, Applicant has amended claim 9 by replacing [[its]] with the patient identification information from the wristband.

Applicant respectfully submits that each of these clarifying amendments to claims 1, 6, and 9 properly address the Examiner's objections and requests that each of these objections be withdrawn.

Patentability under 35 U.S.C. § 103

(A) Non-obviousness of Claims 1-14

Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ahlin *et al.*, U.S. Patent Application Publication No. 2002/0095238 [Ahlin] in view of Csore *et al.*, U.S. Patent Application Publication No. 2002/0013523 [Csore].

With respect to claim 1, the Examiner cites Ahlin for allegedly teaching (1) assigning to each patient a bar code, used as a patient identifier and worn as a wristband; (2) storage of information regarding medications or supplies for a particular patient in a system database; (3) allocating from a supply of bins a specific bin in which the patient's medications/supplies are kept; (4) placement of an identical bar code (that is the same as the patient identifying bar code) on the bins and storage of the patient information in a system database; (5) that prescriptions for medications include patient identifying information; and (6) that when a patient is to be provided medication from his/her individual bin, which is present in the medication cart, the bar code on the wristband of the patient is first scanned by the nurse.

With respect to claim 9, the Examiner cites Ahlin for allegedly teaching (1) assigning a bar code to each patient, which bar code is used as a patient identifier and worn as a wristband; (2) that patient identification information, read from the wristband and a label (including patient identification information), is placed onto a specific bin in which the patient's medications/supplies are kept; (3) that the patient information is stored in a system database; and (4) when a patient is to be provided medication from his/her individual bin, present on the medication cart, that the bar code on the wristband of the patient is first scanned by the nurse.

The Examiner concedes that Ahlin fails to teach Applicant's claimed method of ensuring compatibility between a patient and a treatment specifically for the purpose of blood transfusions. The Examiner alleges, however, that Csore remedies this deficiency in the Ahlin reference by teaching a method of tracking blood transfusions in such a way to ensure compatibility between the patient and the blood. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to use Ahlin's method of ensuring compatibility between medications and patients in view of Csore's method of tracking and matching blood units for transfusion purposes to achieve Applicant's claimed invention.

Applicant respectfully traverses the stated grounds of rejection and submits that the combination of Ahlin and Csore, viewed as a whole, neither teaches nor suggests the invention recited in Applicant's claim 1 or claim 9. Because each of claims 2-8 depend from claim 1 and each of claims 10-14 depend from claim 9, each of claims 2-8 and 10-14 necessarily contain each of the limitations of its corresponding independent claim and are, therefore, also non-obvious over the combination of Ahlin and Csore.

As a preliminary matter, Applicant respectfully submits that the Examiner has not met the burden of setting forth a *prima facie* case of obviousness. More specifically, the Examiner has not provided any showing that one of ordinary skill in the art would have been motivated to combine the Ahlin and Csore references in order to achieve the presently claimed invention. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP § 706.02(j); see, also, *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) wherein the Federal Circuit explains that it is Examiner's burden to demonstrate a "reason, suggestion or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." [underscore added]. In formulating the present bases for rejection, the Examiner has not identified "in the prior art" of record why the ordinarily skilled artisan would have been motivated to combine the Ahlin and Csore references to achieve the presently claimed invention.

Without acquiescing in the Examiner's stated bases for rejecting claim 1 and without conceding that the Examiner has set forth a *prima facie* case of obviousness, Applicant respectfully submits that the present amendments to claim 1 are sufficient to obviate the present rejection under 35 U.S.C. § 103(a).

The Ahlin reference, which the Examiner relies upon as a primary basis for rejection, is directed to an automated pharmaceutical management and dispensing system. Ahlin does not, in

any way, teach a method for tracking blood transfusions as presented in claim 1. Moreover, Ahlin does not address, much less solve, the unique problem of ensuring that a properly allocated blood transfusion unit is administered to the intended patient. Thus, Ahlin cannot be said to teach or suggest the presently claimed invention.

Claim 1, as presently amended, is directed to a method for tracking blood transfusions. The method of claim 1 comprises, *inter alia*, the following steps: (a) collecting a blood sample from the patient and testing said blood sample to determine the type of blood required by the patient, (b) marking a blood transfusion unit with an identifying code, (c) labelling an allocated blood transfusion unit with a compatibility label that comprises an identifying code, and (d) comparing the identifying code marked on the patient allocated blood unit with the identifying code on the compatibility label on said patient allocated blood transfusion unit.

At least two aspects of presently amended claim 1 are not disclosed within the Ahlin reference. First, Ahlin does not teach or suggest collecting a blood sample from a patient and testing the blood sample to determine the type of blood required by the patient. Indeed, Ahlin in no way suggests that a determination of blood type is relevant to the disclosed system for allocation of patient medications. Secondly, Ahlin neither teaches nor suggests the step of ensuring that a compatibility label is affixed to an allocated medication. In fact, and as pointed out by the Examiner, Ahlin teaches affixing patient identifying information to a bin that contains medications and/or supplies. Ahlin does not teach or suggest affixing a label directly onto the medication and/or comparing an identifying label on the medication to an identifying label on a compatibility label. Applicant's claim incorporates this step in order to ensure that the compatibility label is applied to the properly allocated blood unit.

Csore fails to remedy these or other deficiencies in the Ahlin reference because Csore neither teaches nor suggests the essential step of comparing an identifying label on an allocated blood unit with a corresponding identity label on a compatibility label. It is, therefore, urged that the combination of Ahlin in view of Csore would not have rendered claim 1 obvious to one of ordinary skill in the art at the time of the present invention and that the present rejection of claim 1 under 35 U.S.C. §103(a) may be properly withdrawn.

Claim 9, as presently amended, is directed to a method for collecting and storing in a computer database information about blood transfusions. The method of claim 9 comprises, *inter alia*, the steps of: (a) obtaining a blood sample from the patient, (b) applying a blood sample identification label to the blood sample, (c) marking a blood unit with a unique blood unit identification code, (d) printing and applying to a blood unit a compatibility label that includes patient identification information and the blood unit identification code, (e) comparing the blood unit identification code on the compatibility label with the blood unit identification code on the blood unit, and (f) providing an alarm if the patient identification information from the wristband does not match the patient identification information on the compatibility label or if the blood unit identification code on the compatibility label does not match the blood unit identification code on the blood unit.

In contrast to the method presented by instant claim 9, and as discussed above in reference to instant claim 1, Ahlin is directed to an automated pharmaceutical management and dispensing system. Ahlin does not relate, in any aspect, to a method for collecting and storing in a computer database information about blood transfusions as presented in claim 9. Thus, Ahlin cannot be said to teach or suggest the presently claimed invention.

At least the following aspects of present claim 9 are not disclosed within the Ahlin reference. Ahlin neither teaches nor suggests (1) obtaining a blood sample from a patient, (2) applying a blood sample identification label to a blood sample, (3) marking a blood unit with a unique blood unit identification code, (4) printing and applying, to a blood unit, a compatibility label that includes both patient identification information and a blood unit identification code, (5) comparing a blood unit identification code on a compatibility label with a blood unit identification code on the blood unit, or (6) providing an alarm if the patient identification information from the wristband does not match the patient identification information on the compatibility label or if the blood unit identification code on the compatibility label does not match the blood unit identification code on the blood unit.

In combination, these aspects of the presently claimed invention address the problem in the art that patients in need of a blood transfusion receive, at a higher than acceptable frequency, incompatible blood units. The invention of claim 9 therefore includes the steps of comparing a

blood unit identification code on a compatibility label with a blood unit identification code on a blood unit, thereby ensuring that a patient having a certain blood type and/or other requirements receives a blood unit that is compatible with those requirements. In furtherance of these objectives, claim 9 additionally provides an alarm that alerts the caregiver if patient identification information from a wristband does not match patient identification information on compatibility label or if the blood unit identification code on a compatibility label does not match a blood unit identification code on a blood unit. None of these aspects of the present invention are taught or suggested by the Ahlin reference.

Csore fails to remedy these or other deficiencies in the Ahlin reference because Csore neither teaches nor suggests (1) comparing a blood unit identification code on a compatibility label with a blood unit identification code on a blood unit or (2) an alarm that alerts the caregiver if patient identification information from a wristband does not match patient identification information on compatibility label or if the blood unit identification code on a compatibility label does not match a blood unit identification code on a blood unit. It is, therefore, urged that the combination of Ahlin in view of Csore, even if appropriate, would not have rendered claim 9 obvious to one of ordinary skill in the art at the time of the present invention and that the present rejection of claim 9 under 35 U.S.C. §103(a) may be properly withdrawn.

As noted above, each of claims 2-8 depend from claim 1 and each of claims 10-14 depend from claim 9. It necessarily follows from the non-obviousness of claims 1 and 9, therefore, that claims 2-8 and 10-14 are also each non-obvious over the art of record. Applicant, therefore, respectfully requests reconsideration and withdrawal of the present bases for rejecting claims 1-14.

(B) Non-obviousness of Claims 15-20

Claims 15-20 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ahlin in combination with Csore and in further view of Zerhusen *et al.*, U.S. Patent Application Publication No. 2003/0052787 [Zerhusen].

With respect to claim 15, the Examiner cites Ahlin in combination with Csore for the teachings described above in connection with the discussion of the patentability of claims 1-14.

The Examiner further alleges that Ahlin teaches a lock for the medication/supply bins and also that the bins include RF chips.

The Examiner concedes that the combination of Ahlin and Csore fails to teach the caregiver having an RFID tag. The Examiner alleges, however, that Zerhusen remedies this deficiency in the combined references by teaching (1) 'an RFID sensor for receiving identification information from RFID tags associated with a caregiver, a patient, medication [ ], locked medication box [ ], or other equipment or supplies' and (2) 'an RFID sensor [ ] that detects an RFID tag worn by a nurse, and display caregiver icons [ ] upon determining from identification information transmitted by the tag that the nurse is an authorized caregiver.' Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to use the nurse's RFID tag taught by Zerhusen in place of the nurse identity ID badges used by Ahlin and that the artisan would have been motivated to use an RFID tag in order to store more information than the nurse's name, thereby achieving the presently claimed invention.

Applicant respectfully traverses the stated grounds of rejection and submits that the combination of Ahlin, Csore, and Zerhusen, viewed as a whole, neither teaches nor suggests the invention recited in Applicant's claim 15. Because each of claims 16-20 depend from claim 15, each of claims 16-20 necessarily contain each of the limitations of its corresponding independent claim and are, therefore, also non-obvious over the combination of Ahlin, Csore, and Zerhusen.

As a preliminary matter, and as discussed above in reference to the patentability of claims 1-14, Applicant respectfully submits that the Examiner has, again, not met the burden of setting forth a *prima facie* case of obviousness because the Examiner has not provided any showing that one of ordinary skill in the art would have been motivated to combine the Ahlin, Csore, and Zerhusen references in order to achieve the presently claimed invention. The Examiner has not identified "in the prior art" of record why the ordinarily skilled artisan would have been motivated to combine the Ahlin, Csore, and Zerhusen references to achieve the presently claimed invention.

Claim 15 is directed to an apparatus for tracking the movement of blood products. The apparatus of claim 15, as presently amended, comprises, *inter alia*, (a) a blood product identification tag attached to units of blood products, each blood product identification tag

encoding a unique blood product identification code; (b) a refrigerated storage means for storing blood products; (c) a tag reading means associated with the storage means for reading blood product identification codes and caregiver identification codes; and (d) a computer coupled to a tag reading means, the computer including software for recording blood product identification codes for each blood product stored in the storage means and for recording the caregiver identification code for each caregiver who accesses the storage means.

Applicant discusses, above, the deficiencies in the teachings of Ahlin and Csore in reference to the inventions of claims 1 and 9. Ahlin is directed to an automated pharmaceutical management and dispensing system. The focus of this reference is "to have patient medications delivered faster in an institutional setting... [E]xisting systems are so laborious that such timely deliveries of medications are virtually impossible." (see, *e.g.*, p. 1, ¶ 0009). Ahlin does not teach or suggest an apparatus for tracking the movement of blood products. Moreover, Ahlin does not address the problem overcome by the present invention of administering improperly matched blood to a blood transfusion patient.

The unique aspects Applicant's claim 15 are simply not addressed and/or presented within the Ahlin reference. More specifically, Ahlin does not teach or suggest (a) blood product identification tags attached to units of blood products wherein each blood product identification tag encodes a unique blood product identification code; (b) a refrigerated storage means for storing blood products; (c) a tag reading means associated with the blood storage means for reading blood product identification codes and caregiver identification codes; and (d) a computer coupled to the tag reading means, wherein the computer includes software for recording blood product identification codes for each blood product stored in the refrigerated storage means and for recording the caregiver identification code for each caregiver who accesses the storage means.

In contrast to the apparatus of claim 15, Ahlin's system for management and dispensing of pharmaceuticals does not provide for the attachment of identification tags directly to the medications or other medical elements within the individual patient bins. Rather, identification labels are affixed to the bins themselves. Thus, Ahlin does not teach or suggest affixing unique identification codes as contemplated by the presently claimed invention. Furthermore, because Ahlin is concerned with management and dispensing of pharmaceuticals, and not blood units,

Ahlin's system does not incorporate a refrigerated storage means and recited in claim 15. Because Ahlin does not directly attach an identification tag and/or caregiver identification code to the medications and other medical elements, Ahlin cannot be said to suggest, much less teach, the use of a tag reading means and/or a computer coupled to a tag reading means in order to read and/or record product identification codes for each blood product stored and caregiver identification codes for each for each caregiver accessing the refrigerated storage means.

None of these deficiencies in the Ahlin reference are overcome by either one or both of the Csore or Zerhusen references. It is, therefore, urged that the combination of Ahlin and Csore, in view of Zerhusen, would not render Claim 15 obvious to one of skill in the art, and that the present rejection of the Claims 15-20 under 35 U.S.C. §103(a) may be properly withdrawn.

Conclusion

In view of the above amendments and remarks, Applicant believes that all of the Examiner's concerns have been addressed. Early reconsideration and allowance of the amended claims is respectfully requested.

Respectfully submitted,

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